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P/546-279 REISSUE

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In re Patent Application of

New York, New York

William STERN

Date: May 5, 2004

Serial No.: 10/774,358

Group Art Unit: 1616

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For: NASAL CALCITONIN FORMULATION

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

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Dorothy Jenkins
Signature

May 5, 2004

Date of Signature

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Enclosure

Respectfully submitted,


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APPLICANT'S ART CITATION (Use several sheets if necessary)		Application 10/774,358		OFGS File No. P/546-279 REISSUE			
		Applicant William Stern					
		Filing Date February 5, 2004		Group Art Unit 1616			
U.S. PATENT DOCUMENTS							
Examiner Initial	Document Number	Date MM-YYYY	Name	Class	Sub-class	Filing Date If Appropriate	
	US-6,087,338	07-2000	Veronesi et al.	514	21	Aug. 8, 1997	
	US-6,107,277	08-2000	Veronesi et al.	514	12	Aug. 8, 1997	
	US-5,124,315	06-1992	Ceschel et al.	514	12	Jun. 17, 1991	
	US-5,183,802	02-1993	Aliverti et al.	514	2	Nov. 14, 1988	
	US-5,026,825	06-1991	Grebrow et al.	530	307	Sep. 8, 1988	
	US-5,759,565	06-1998	Azria et al.	424	434	Dec. 31, 1991	
	US-4,788,221	11-1998	Kagatani et al.	514	808	May 5, 1988	
	US-5,059,587	10-1991	Yamamoto et al.	514	12	Jun 19, 1998	
	US-5,665,700	09-1997	Cho et al.	514	2	Aug 15, 1994	
	US-6,149,893	11-2000	Mardente et al.	424	45	Mar 1, 1999	
FOREIGN PATENT DOCUMENTS							
	Document Number	Date MM-YYYY	Country	Class	Sub-class	Translation	
						Yes	No
	0 809 512	12-1997	Europe				
	0 115 627	08-1984	Europe				
	0 418 697	03-1990	Europe				
	0 358 234	03-1990	Europe				
	0 327 756	08-1989	Europe				
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	A	Dua et al., International Journal of Pharmaceutics 147, 1997, pp. 233-242 "The influence of tonicity and viscosity on the intranasal absorption of salmon calcitonin in rabbits."					
	B	P. Graf et al., Clin. Exp. Allergy, Vol. 25:395-400; 1995 "Benzalkonium chloride in a decongestant nasal spray aggravates rhinitis medicamentosa in healthy volunteers"					
	C	H. Hallen et al., Clin. Exp. Allergy, Vol. 25:401-405; 1995 "Benzalkonium chloride in nasal decongestive sprays has a long-lasting adverse effect on the nasal mucosa of healthy volunteers"					
	D	Berg et al., Laryngoscope 104:1153-1158; 1994 "The Effect of Decongestive Nosedrops on Human Respiratory Mucosa In Vitro"					
	E	P.C. Braga et al., J. Pharm. Pharmacol. 44:938-940; 1992 "The effects of calcitonin nsala preparations and their excipients on mucociliary clearance in an ex-vivo frog palate test"					
	F	Observations on European Patent Application No. EP 1251867 (third party observations)					
Examiner			Date Considered				
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U.S. PATENT DOCUMENTS							
Examiner Initial	Document Number	Date MM-YYYY	Name	Class	Sub-class	Filing Date If Appropriate	
	US-4,690,952	09-1987	Kagatani, et al.	514	11	Nov. 22, 1985	
	US-5,023,252	06-1991	Hseih	514	183	Dec. 8, 1989	
	US-5,534,496	07-1996	Lee et al.	514	17	Mar. 29, 1994	
	US-5,536,508	07-1996	Canal et al.	424	501	Oct. 21, 1993	
	US-5,654,000	08-1997	Poli et al.	424	450	Jul. 17, 1996	
	US-5,714,477	02-1998	Einarsson	514	56	Dec. 4, 1995	
	US-5,719,122	02-1998	Chiodini, et al.	514	424	Jun. 19, 1995	
	US-5,733,572	03-1998	Unger et al.	424	450	Nov. 29, 1994	
FOREIGN PATENT DOCUMENTS							
	Document Number	Date MM-YYYY	Country	Class	Sub-class	Translation	
						Yes	No
	0 371 010	05-1990	Europe				
	0 418 697	03-1991	Europe				
	0 489 217	06-1992	Europe				
	0 726 075	08-1996	Europe				
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	G	Remington, The Science and Practice of Pharmacy, 20 th Edition, Philadelphia (USA) Jan. 2000, Chapter 47, pages 922-3					
	H	Patent family search for EP 0358 234 (equiv. USP 5,026,825), 1/34/1 Dialog(R) File 351: Derwent abstract, 008189979, "Intranasal calcitonin formulations - contg. Delta-amino-laevulinic acid for enhanced bioavailability".					
	I	Patent family search for EP 0327756, 2/34/1 Dialog(R) File 351: Derwent abstract, 007943804, "Pharmaceutical Calcitonin - contg. for nasal glycyrrhizinate to enhance mucosal membrane absorption, esp. for nasal administration".					
	J	Repertorio Farmaceutico Italiano, REFI 4a Edizione (REFI 4 th Edition), 1990, page A 212, (Calcitonina Spray Nasale Armour", and page A223 "Carbicalcin Spray", Farmindustria, Associazione Nazionale dell'Industria Farmaceutica (National Association of the Pharmaceutical Industry) - CEDOF Editor, 1990					
	K	The Merck Index, 13 th Edition, 2001, page 3576					
	L	Physicians' Desk Reference-PDR 53 Edition 1999, pages 2057-59					
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	US-5,700,486	12-1997	Canal et al.	424	501	Apr. 30, 1996
	US-5,725,871	03-1998	Illum	424	434	Jun. 15, 1994
	US-5,759,566	06-1998	Poli et al.	424	434	Jun. 17, 1996
	US-6,509,006	01-2003	Platz et al.	424	46	Oct. 26, 1999
	US-6,447,785	09-2002	Donovan	424	239	Nov. 2, 2000
	US-6,440,446	08-2002	Yoshizane et al.	424	423	Apr. 16, 1999
	US-6,440,392	08-2002	Stern	424	43	Feb. 2, 2001
	US-6,348,207	02-2002	Milstein et al.	424	408	Sep. 30, 1997
	US-6,153,582	11-2000	Skelnik	514	12	Nov. 5, 1998
	US-6,086,918	07-2000	Stern et al.	424	474	Mar. 14, 1997
	US-6,017,538	01-2000	Druihlhe et al.	424	191	Oct. 18, 1993
	US-5,968,899	10-1999	Sekine et al.	514	3	Jun. 2, 1995
	US-5,938,654	08-1999	Wong et al.	604	892	Feb. 1, 1995
	US-5,912,014	06-1999	Stern et al.	424	474	Mar. 15, 1996
	US-5,858,391	01-1999	Cuca et al.	424	439	May 28, 1997
	US-5,776,886	07-1998	Inamoto et al.	514	2	Jun. 2, 1994
	US-5,726,154	03-1998	Baudys et al.	514	12	Jun. 28, 1996
	US-5,693,608	12-1997	Bechgaard et al.	514	2	Feb. 28, 1995
	US-5,637,309	06-1997	Tajima et al.	424	423	Sep. 20, 1994
	US-5,593,962	01-1997	Arvinte et al.	514	12	Aug. 4, 1993
	US-5,571,788	11-1996	Arvinte et al.	514	12	Jan. 24, 1994
	US-5,496,801	03-1996	Holthuis et al.	514	12	Dec. 23, 1993
	US-5,310,727	05-1994	Lattanzi et al.	514	12	Nov. 30, 1990
	US-5,281,580	01-1994	Yamamoto et al.	514	12	Jul. 23, 1991
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Examiner Initial	Document Number	Date MM-YYYY	Name	Class	Sub-class	Filing Date If Appropriate
	US-5,279,836	01-1994	Nicolaus	424	484	Jan. 30, 1992
	US-5,234,906	08-1993	Young et al.	514	12	Jan. 10, 1991
	US-4,900,730	02-1990	Miyauchi	514	12	Jun. 18, 1987
	US-4,845,080	07-1989	Fischer	514	12	Sep. 26, 1986
	US-4,151,276	04-1979	Caulin et al.	424	11	May 12, 1975
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
	M	Romeijn S.G., et al., INT. J. PHARM., 1996, 135/1-2 (137-145), "The Effect of Nasal Drug Formulations on Ciliary Beating <i>in vitro</i> ", abstract				
	N	Schipper N.G.M., et al., CALCIF. TISSUE INT., 1995, 56/4 (280-282), "Methylated (beta)-cyclodextrins are Able to Improve the Nasal Absorption of Salmon Calcitonin", abstract				
	O	Martin E., Pharm. Res., 1997 May, 14 (5): 631-7, "Confocal Laser Scanning Microscopic Visualization of the Transport of Dextran After Nasal Administration to Rats: Effects of Absorption Enhancers", abstract				
	P	Abe K., et al., Chem. Pharm. Bull (Tokyo) 1995 Dec.; 43 (12): 2232-7, "Enhanced Nasal Delivery of Luteinizing Hormone Releasing Hormone Agonist Buserelin by Oleic Acid Solubilized and Stabilized in Hydroxypropyl-beta -cyclodextrin", abstract				
	Q	Kagatani S., et al., Pharm. Res. 1996 13/5 (739-743), "Enhancement of Nasal Salmon Calcitonin Absorption by Lauroylcarnitine Chloride in Rats", abstract				
	R	Morimoto K., et al., J. Pharma. Pharmacol. 1985 37/2 (134-136) "Enhancement of Nasal Absorption of Insulin and Calcitonin Using Polyacrylic Acid Gel", abstract				
	S	Caspar W.R., et al., Drug & Cosmetic Industry, Vol. 156; No. 1; p. 46, "New Ways of Enhancing the Delivery of Skin Care Ingredients", abstract				
	T	Ratafia, Manny, et al., M&M Medical Marketing & Media, Vol 24; No. 11, p. 10, "Drug Delivery: the Key to Biotechnology Markets", abstract				
	U	Biotechnology Newswatch, Vol. 9, No. 12; p. 1, "Two-nasally delivered CalBio hormones pass initial clinicals", abstract				
	V	Martin E., et al., Pharm Res 1997 May; 14(5) : 631-7, "Confocal laser scanning microscopic visualization of the transport of Dextran after Nasal Administration to Rats: Effects of Absorption Enhancers", abstract				
	W	Kurosaki Y., et al., J. Pharmacobiodyn 1988 Dec; 11 (12) : 824-32, "Application of Propranolol to the Keratinized Oral Mucosa: Avoidance of First-Pass Elimination and the Use of 1-Dodecylazacycloheptan-2-one (Azone) as an Absorption Enhancer of Bioadhesive Film-Dosage Form", abstract				
	X	Okamoto H., et al., J. Pharm. Pharmacol 1987 Jul; 39 (7) : 531-4, "Enhanced penetration of mitromycin C through hairless mouse and rats skin by enhancers with terpene moieties", abstract				
	Y	Sugibayashi K., et al., J. Pharm. Pharmacol 1985 Aug; 37 (8) : 578-80, "Effect of the Absorption Enhancer, Azone, on the Transport of 5-Fluorouracil Across Hairless Rat Skin", abstract				
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	Z	Vermehren C., et al., Drug Metab Dispos 1997 Sep; 25 (9): 1083-8, "Absorption and Metabolism of the Absorption Enhancer Didecanoylphosphatidylcholine in Rabbit Nasal Epithelium <i>in vivo</i> ", abstract	
	AA	Jacobs M.A., et al., Diabetes 1993, Nov; 41 (11) : 1649-55, "The pharmacodynamics and activity of intranasally administered insulin in healthy male volunteers", abstract	
	BB	Schipper N.G., et al., Pharm Res 1996 Nov; 13 (11) : 1686-92, "Chitosans as Absorption Enhancers for Poorly Absorbable Drugs. 1: Influence of Molecular Weight and Degree of Acetylation on Drug Transport Across Human Intestinal Epithelial (Caco-2) Cells", abstract	
	CC	Pillion D.J., et al., J. Pharm. Sci. 1995 Nov; 84 (11) : 1276-9, "DS-1, A Modified Quillaja Saponin, Enhances Ocular and Nasal Absorption of Insulin", abstract	
	DD	Agerholm C., et al., J. Pharm. Sci. 1994 Dec; 83 (12) : 1706-11, "Epithelial Transport and Bioavailability of Intranasally Administered Human Growth Hormone Formulated with the Absorption Enhancers Didecanoyl-L-alpha-phosphatidylcholine and alpha-cyclodextrin in Rabbits", abstract	
	EE	Critchley H., et al., J. Pharm Pharmacol 1994 Aug; 46 (8) : 651-6, "Nasal Absorption of Desmopressin in Rats and Sheep. Effect of A Bioadhesive Microsphere Delivery System", abstract	
	FF	Santus G., et al., Farmaco 1993 Dec; 48 (12) : 1709-33, "Nasal Formulations of Ketorolac Tromethamine: Technological Evaluation -- Bioavailability and Tolerability in Rabbits", abstract	
	GG	Donovan M.D., et al., Pharm. Res. 1990 Aug; 7 (8) : 808-15, "The Molecular Weight Dependence of Nasal Absorption: the Effect of Absorption Enhancers", abstract	
	HH	Pontiroli A.E., et al., Eur J Clin Pharmacol 1989; 37 (4) : 427-30, "Nasal Administration of Glucagon and Human Calcitonin to Healthy Subjects: A Comparison of Powders and Spray Solutions and of Different Enhancing Agents", abstract	
	II	Shao Z., et al., Pharm Res 1992 Sep; 9 (9) : 1157-63, "Cyclodextrins as Nasal Absorption Promoters of Insulin : Mechanistic Evaluations", abstract	
	JJ	Sarkar M.A., Pharm Res 1992 Jan; 9 (1) : 1-9, "Drug Metabolism in the Nasal Mucosa", abstract	
	KK	Morimoto K., et al., Pharm Res 1991 Sep; 8 (9) : 1175-9, "Effects of Proteolytic Enzyme Inhibitors on the Nasal Absorption of Vasopressin and an Analogue", abstract	
	LL	Hosoya K., et al., Biol Pharm Bull 1994 Feb; 17 (2) : 316-22, "Evaluation of Enhancers to Increase Nasal Absorption Using Ussing Chamber Technique", abstract	
	MM	Tengamnuay P., et al., Pharm Res 1990 Apr; 7 (4) : 370-5, "Bile Salt-Fatty Acid Mixed Micelles as Nasal Absorption Promoters of Peptides. II. In vivo Nasal Absorption of Insulin in Rats and Effects of Mixed Micelles on the Morphological Integrity of the Nasal Mucosa", abstract	
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